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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,349	12/19/2001	Yasuki Kato	5.1195	1803
5514	7590	11/01/2004	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/018,349

### Applicant(s)

KATO ET AL.

### Examiner

Gollamudi S Kishore, Ph.D

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16,19,20,22-25,35-39 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,19,20,22-25,35-39 and 42-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9-27-04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims included in the prosecution are 16, 19-20, 22-25, 35-39 and 42-48.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 16, 19-20, 23, 25, 35, 37, 39, 42-44 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodle (5,356,633) or Woodle (5,014,556).

Woodle discloses a method of preparation of multilamellar vesicles (MLVs) containing a drug. The liposome sizes are 160 nm. The drugs include both steroidal and non-steroidal anti-inflammatory agents and anticancer agent, methotrexate. The liposomes are made from either hydrogenated soy phosphatidylcholine or PEG-DSPE (note the abstract, Examples, Example 4 in particular and claims).

Similarly, Woodle (556) discloses liposomes containing a drug. The liposome sizes are either 160 or 170 nm. The liposomes are made from either hydrogenated soy phosphatidylcholine or PEG-DSPE (abstract, Examples 4 and 7).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant is incorrect in stating that Woodle does not teach instant

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composition of liposomes and its sizes. The examples 4 and 7 clearly teach instant composition.

3. Claims 16, 23, 24, 25, 35, 37, 38, 39, 42 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen (4,920,016).

Allen discloses liposomes made from DSPC and having a diameter of 170 nm. The active agents include anti-tumor agents and antibiotics (abstract, columns 10-11, Table 1 in Example 3).

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 16, 19-20, 22-23, 25, 35-39 and 42-46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 850,646 of record by itself or Woodle 633 cited in the previous action.

EP discloses liposome formulations containing indolocarbazole (anti-cancer agent) derivatives. The liposomes are made from hydrogenated phospholipids and PEG-DSPE (note abstract, page 4, Examples and claims). Although, EP does not explicitly state that the sizes of the liposomes, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to prepare liposomes of desired sizes with the

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expectation of obtaining the best possible results. One of ordinary skill in the art would be motivated to prepare liposomes of instant sizes since the references of Woodle show the routine practice in the art of preparing liposomes of different sizes.

6. Claims 24 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodle 633 or 556 cited above by themselves or in view of (Mauer, BBA, 1998, 1374, pp., 9-20) of record.

As pointed out above, Woodle discloses a method of preparation of multilamellar vesicles (MLVs) containing a drug. The liposome sizes are 160 nm. The drugs include both steroidal and non-steroidal anti-inflammatory agents and anticancer agent, methotrexate. The lipids used for the preparation of MLVs are PEG-DSPE, DPPC, DSPC (note the abstract, Examples, Example 4 in particular and claims). Although Woodle does not teach the encapsulation of antibiotics or the claimed specific cancer drug it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated within the liposomes based on the guidance provided by Woodle. One of ordinary skill in the art would be motivated further to encapsulate these compounds the reference of Mauer which teaches the knowledge in the art of encapsulation of the antibiotic, ciprofloxacin in the liposomes (note the abstract). One of ordinary skill in the art would expect similar encapsulation.

Applicant's arguments have been fully considered, but are not found to be persuasive. The examiner had already addressed applicant's arguments regarding Woodle. Applicant provides no specific arguments with regard to Mauer. The rejection is maintained.

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7. Claims 22 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodle 633 or 556 cited above in combination with EP cited above.

What is lacking in Woodle is the teaching of indolocarbazole derivatives as the active agent. However, it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated within the liposomes based on the guidance provided by Woodle, especially in view of EP which teaches the knowledge in the art of encapsulation of this compound in the liposomes. One of ordinary skill in the art would expect similar encapsulation.

Applicant's arguments have been fully considered, but are not found to be persuasive. The examiner had already addressed applicant's arguments regarding Woodle. Applicant provides no specific arguments with regard to EP. The rejection is maintained.

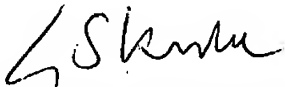
US 6,090,406 and 6,355,268 are cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK